GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3274
ANSWERED ON:05.08.2016
Animal Testing of New Drugs
Hari Shri G.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has banned the repeat animal testing of new drugs which were already tested abroad and if so, the details thereof; and

(b) whether the ban falls under the amendment schedule Y, and if so, the details thereof?

Answer

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND
FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)
(a) & (b): The Government has vide GSR No. 313 (E) dated 16.03.2016 amended Appendix I to Schedule Y to Drugs and Cosmetics Rules,1945 to inter alia provide that where data on animal toxicity as per specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.
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